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Re-evaluation Decision RVD2011-02

Thiabendazole

(publié aussi en français)

17 March 2011

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-1017 (print)
1925-1025 (online)

Catalogue number: H113-28/2011-2E (print version)
H113-28/2011-2E-PDF (PDF version)

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Re-evaluation Decision

After a re-evaluation of the pesticides containing thiabendazole, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing thiabendazole for sale and use in Canada.

An evaluation of available scientific information found that products containing thiabendazole do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of thiabendazole uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of thiabendazole was first presented in Proposed Re-evaluation Decision PRVD2010-12, *Thiabendazole*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of thiabendazole as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-12. To comply with this decision, registrants of products containing thiabendazole will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Thiabendazole, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of thiabendazole. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

The USEPA re-evaluated thiabendazole and published its conclusions in a 2002 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2010-12, *Thiabendazole*.

What Is Thiabendazole?

Thiabendazole is a fungicide that is used to control fungal diseases on fruits and vegetables. Thiabendazole is applied as a postharvest spray treatment on apples, pears, potatoes and chicory roots (intended for Belgian endive production), a drench on white button mushrooms, and as a pre-planting treatment of chickpea and lentil seed. Thiabendazole is also registered for use in control of Dutch elm disease in elm trees and as a material preservative in paints, adhesives, paper and textiles.

Health Considerations

Can Approved Uses of Thiabendazole Affect Human Health?

Thiabendazole is unlikely to affect your health when used according to the revised label directions.

People could be exposed to thiabendazole by consuming food and water, working as a mixer/loader/applicator, by entering treated sites or by handling thiabendazole-treated products. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that thiabendazole was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and similar risk-reduction measures are required. Additional mitigation measures are required based on risk assessments conducted by the PMRA.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Thiabendazole is currently registered in Canada for use on apples, pears, potato, and chicory root, white button mushrooms and on chickpea and lentil seed, and could be used in other countries on crops that are imported into Canada. The following specific MRLs have been established: apple (wet pomace) 10 ppm, pear 10 ppm, potato 10 ppm, citrus fruit 10 ppm, banana 0.4 ppm and endive (chicory roots) 0.05 ppm. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the December 2009 Information Note, *Progress on Minimizing Reliance on the 0.1 Parts per Million as a General Maximum Residue Limit for Food Pesticide Residue.*

Environmental Considerations

What Happens When Thiabendazole Is Introduced Into the Environment?

Thiabendazole is unlikely to affect non-target organisms when used according to the revised label directions.

Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that thiabendazole was unlikely to adversely affect the environment and, the reregistration of thiabendazole was acceptable. No additional mitigation measures were required by the USEPA. These conclusions apply to the Canadian situation. Based on PMRA practices, general environmental hazard label statements are required by the PMRA.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of thiabendazole, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional PPE for workers involved in the post-harvest treatment of food commodities and, for on-farm and commercial seed treatment activities, and tree treatment.
- A 12-hour restricted-entry interval (REI) for all agriculture uses.
- A limit of potato tubers treated per day to 500,000 kg per worker.
- Restriction of post-harvest application methods to mechanical sprayer application only.
- Restriction of seed treatment methods to commercial and on-farm treaters using auger treatments only.
- Packaging of powder end-use formulation in water soluble pouches.
- Rate reduction to 0.2% thiabendazole in paint.
- Limitation of thiabendazole-treated materials to non-food use only.

Environment

- General environmental hazard label statements for aquatic species and effluent discharge.

Appendix I lists all required label amendments.

Other Information

Any person may file a notice of objection[3] regarding this decision on thiabendazole within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing Thiabendazole

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) For agriculture uses of thiabendazole the following statements must be included in the **PRECAUTIONS** section:

> Do not enter or allow the entry into treated areas until 12 hours after application.

II) For agriculture uses of thiabendazole the following statement must be included in the **DIRECTIONS FOR USE** section.

> Workers must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves during mixing, loading, treating, clean-up, and repair.
>
> For post-harvest treatment of commodities, apply using mechanical sprayer only.
>
> A limit of 500,000 kg potato tubers may be treated per day per worker

III) For seed treatment uses of thiabendazole the following statements must be included in the **PRECAUTIONS** section:

> On-Farm seed treatment
> Workers must wear coveralls over a long-sleeved shirt and long pants, hat, chemical-resistant gloves, and a dust mask during mixing, loading, treating, clean-up, and maintenance of seed treatment equipment.
>
> Commercial seed treatment
> Workers must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves during mixing, loading, treating, clean-up, maintenance of seed treatment equipment, and bagging, sewing or stacking of bagged treated seed. Wear a suitable dust mask when bagging or sewing bags of treated seed or when transferring seed to a storage bin.

All bags containing treated seed for sale or use in Canada must be labelled or tagged as follows:

> This seed has been treated with Seed Protectant Fungicide containing thiabendazole. Wear a long-sleeved shirt, long pants, and chemical resistant gloves when handling treated seeds. Do not use for food and feed. Store away from food and feed.

IV) For seed treatment uses of thiabendazole the following statements must be included in the **DIRECTIONS FOR USE** section:

> For use by commercial treaters and on-farm treaters using auger treating only.

V) For seed treatment uses of thiabendazole the following application equipment must be removed from the **GENERAL INFORMATION** section:

> hopper box and seed drill

VI) For tree treatment uses of thiabendazole the following statement must be included in the **PRECAUTIONS** section:

> Workers must wear a long-sleeved shirt and long pants, and chemical-resistant gloves when handling the product.

VII) For material preservative uses of thiabendazole the following statement must be included in the **PRECAUTIONS** section:

> Workers must wear a long-sleeved shirt, long pants and chemical-resistance gloves during mixing, loading, clean-up and repair activities.

VIII) For paint uses of thiabendazole the **DIRECTIONS FOR USE** section must be amended to reflect rate reduction from 0.3% a.i. to 0.2% a.i.

IX) Powder formulation of thiabendazole must be packaged in water soluble pouches. For the replacement products packaged in water soluble bags, the following aspects must be considered when revising the label:

> Pouch size must accommodate application rate.
> Label must include a component for the water soluble bag.

X) For powder formulations packaged in water soluble pouches the following statement must be included in the **PRECAUTIONS** section:

> HANDLING PRECAUTIONS: Do not handle the inner bag with wet gloves as the bag will begin to dissolve on contact with even a small amount of water. Do not open the inner bags or attempt to remove the product from them. The water soluble packet is not designed to be remeasured or subdivided. The inner bag should not be opened and partial bag not used. The entire contents of the inner (water soluble) bag must be used.

XI) For powder formulations packed in water soluble pouches the following statement must be included in the **STORAGE** section:

> Do not remove pouch from overwrap container except for immediate use.
> Do not allow to become wet in storage. Keep container closed when not in use.

XII) For material preservative uses (adhesives and paper products) of thiabendazole the following label statement must be included on the **primary panel**:

> For use as a material preservative to control fungi in non-food contact materials and products.

XIII) For all uses of thiabendazole the following statements must be included in the **ENVIRONMENTAL HAZARDS** section:

> Toxic to aquatic organisms.
>
> DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.
>
> DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans and other waters.